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## **Programs, Practices, People**

- 193 Results of study on use of nutrition labels on food packages
- 193 First issue of new journal, *Sociology of Health and Illness*, scheduled for spring 1979
- 193 Clearinghouse for information on arthritis set up at NIH
- 194 Collaborative graduate program in podiatric public health □ *Bal K. Kerath, Wadie W. Kemel, and Robert G. Ballard*
- 194 Pilot quality assurance curriculum for dental schools
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- 195 Supermarket launches pilot program with NHLBI on nutrition education research
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Cover: Twelve agencies of the Department of Health, Education, and Welfare contributed chapters of the new "Surgeon General's Report on Smoking and Health." Major findings of the 1,200 page report are summarized on pages 107 and 108 of this issue.

## Standards are Established for Animal Studies on Safety of FDA-Regulated Products

■ Standards to assure the adequacy and integrity of animal studies on the safety of products regulated by the Food and Drug Administration were published in the Federal Register of December 22, 1978, and will become effective 180 days afterward.

Known as Good Laboratory Practices (GLPs), the standards establish requirements for all laboratories that conduct animal tests intended to be submitted to FDA to demonstrate the safety of a product. FDA estimates that 500 laboratories in the United States and overseas conduct such tests. FDA-regulated products tested in these laboratories include food and color additives, human and animal drugs, medical devices, and electronic products. The need for standards for animal testing laboratories became evident in 1975 when FDA investigations showed that some animal studies had been poorly carried out and that data had been improperly reported.

Failure of a laboratory to comply with the new standards could result in FDA rejection of studies conducted in it or in the FDA's disqualification of the laboratory from conducting further studies. The FDA regulations establish requirements for, among other things, the qualification and training of personnel, the adequacy of animal care and other facilities, equipment design and maintenance, the conduct of a

study, and the storage and retrieval of records and data.

So that animal laboratories will have a single set of standards with which to comply, the standards are being coordinated with other Federal regulatory agencies—the Environmental Protection Agency (EPA), the Consumer Product Safety Commission, and the Occupational Health and Safety Administration. EPA is expected to propose similar regulations in early 1979 to assure the adequacy of animal studies on pesticides, insecticides, and potentially toxic substances.

"Under our regulatory system," FDA Commissioner Donald Kennedy noted, "FDA and other agencies make judgments on products on the basis of safety data submitted by manufacturers. Our experience indicates a need for us to establish more explicit requirements for the facilities in which animal studies are conducted. These new regulations will help assure the integrity and quality of tests submitted to us and thereby provide us with further assurances that the regulatory decisions we make are based on good data."

To conduct inspections at animal testing facilities to see whether they comply with the new standards, 263 investigators and supervisors from FDA offices were trained at the National Center for Toxicological Research in Jefferson, Ark.

## education notes

**Symposium on drugs and chemical risks to the fetus and newborn.** A 2-day symposium on drugs and chemical risks to the fetus and newborn will be held in New York City, May 21–22, 1979. Sponsored by the National Foundation–March of Dimes, the program will be presented by the Downstate Medical Center of the State University of New York.

The purposes of the meeting are to (a) provide health professionals with the most current information about the impact of drugs and environmental

chemicals upon the fetus and newborn, (b) deal with the acute and long-term effects of these substances (not only when the agents are administered prenatally, but also when exposure occurs through breast milk), and (c) stimulate investigation into the mechanisms of the effects of drugs and chemicals, thereby contributing to the prevention of birth defects. For further information, contact the National Foundation–March of Dimes, 622 Third Ave., New York, N.Y. 10017, or phone (212) 682-6430.

## federal register briefs

*Compiled by Charles E. Jackson, Division of Legislation, Health Resources Administration.*

November 15, 1978, Vol. 43, No. 221, pp. 53242–53244

**Psychosurgery.** The Secretary of Health, Education, and Welfare has announced his determinations regarding psychosurgery following the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

The Secretary has determined that (a) the Department will assist leading professional organizations to form a joint committee on psychosurgery to establish mechanisms for the voluntary regulation and reporting of psychosurgical procedures and (b) the Department will promulgate regulations covering any procedures supported by DHEW programs. These regulations will generally follow the Commission's recommendations but would use the procedures with prisoners, children, involuntarily confined mental patients, legally incompetent patients, and any patient who in the judgment of the attending physician was not competent to give informed consent.

November 15, 1978, Vol. 43, No. 221, pp. 53060–53061

**National toxicology program.** The Secretary of the Department of Health,

pliance with the NIH guidelines by companies that carry out DNA research but whose products are not requested by the Food and Drug Administration. He directed NIH to increase its research designed to determine the extent of risk associated with recombinant DNA research. He broadened substantially the public representation on the HEW advisory committee that will assist NIH in administering the revised guidelines. He also increased significantly public access to information about recombinant

DNA research activities and increased public participation in the administration of the guidelines in local communities.

December 22, 1978, Vol. 43, No. 247, pp. 60134-60135

**Announcement on recombinant DNA research by FDA Commissioner.** The Commissioner of the Food and Drug Administration has announced intentions to propose regulations to require

assurances in future submissions to the Agency that any recombinant DNA work which has been or will be performed in connection with the submissions fully comply with the NIH guidelines for recombinant DNA research.

The Food and Drug Administration has received inquiries from pharmaceutical manufacturers and others concerning the use of recombinant DNA techniques in research on, and the development and manufacture of, products subject to the Agency's jurisdiction.

# publications

## FEDERAL

Factors Which Affect the Utilization of Dental Services. *DHEW Publication No. (HRA) 78-64*. 1978; 71 pages.

Analysis of Computer-Based Dental Systems Simulation Models. *DHEW Publication No. (HRA) 78-59*. 1978; 360 pages.

A Directory of Expanded Role Programs for Registered Nurses, 1979. *DHEW Publication No. (HRA) 79-10*. 1979; 30 pages.

Evaluation of Child Abuse and Neglect Demonstration Projects, 1974-1977. Vols. 1 and 2: Child Abuse and Neglect Treatment Programs: Final Report and Summary Findings. *NCHSR Research Report Series. DHEW Publication No. (PHS) 79-3217-1*. August 1978; 138 pages.

Effects of the Payment Mechanism on the Health Care Delivery System. Proceedings of a conference held at Skyland Lodge, Shenandoah National Park, Virginia, November 7-8, 1977. *NCHSR Research Proceedings Series. Edited by William R. Roy. DHEW Publication No. (PHS) 78-3227*. 1978; 138 pages.

Evaluation of Social Work Services in Community Health and Medical Care Programs. Based on the Proceedings of the 1973 Annual Institute for Public Health Workers. *DHEW Publication No. (HSA) 78-5205*. Reprinted 1978; 176 pages.

Health Status of Children: A Review of Surveys, 1963-72. *DHEW Publication No. (HSA) 78-5744*. 1978; 259 pages (Stock No. 017-022-00634-1).

Children at Risk. By Vivian R. Isenstein and William Krasner. *DHEW Publica-*

*tion No. (ADM) 78-724*. 1978; 21 pages (Stock No. 017-024-00763-3).

Caring for Youth. Essays on Alternative Services. By James S. Gordon. *DHEW Publication No. (ADM) 78-557*. 1978; 142 pages (Stock No. 017-024-00579-5).

A National Profile of Catastrophic Illness. *NCHSR Research Summary Series. DHEW Publication No. (PHS) 78-3201*. May 1978; 21 pages.

Criterion Measures of Nursing Care Quality. *NCHSR Summary Series. DHEW Publication No. (PHS) 78-3187*. August 1978; 29 pages.

Nutritional Disorders of Children. Prevention, Screening, and Followup. By Samuel J. Fomon. *DHEW Publication No. (HSA) 78-5104*. Reprinted 1978; 123 pages (Stock No. 017-022-00515-0).

A Self-Instructional Booklet to Aid in the Understanding of the Female Physical Examination for Contraception. *DHEW Publication No. (HSA) 78-5609*. Reprinted 1978, 19 pages.

Equipment Guidelines for Ambulatory Health Centers. *DHEW Publication No. (HSA) 78-5505*. Reprinted 1978.

Identification and Management of Selected Developmental Disabilities: A Guide for Nurses. Edited by Fay F. Russell. *DHEW Publication No. (HSA) 78-5280*. Reprinted 1978; 35 pages.

International Perspectives on Aging. Testimony before the U.S. Senate Special Committee on Aging by Robert N. Butler, November 10, 1977. *DHEW Publication No. (NIH) 79-331*. 1978; 7 pages.

Plan and Operation of the HANES I Augmentation Survey of Adults 25-74 Years, United States, 1974-1975.

*DHEW Publication No. (PHS) 78-1314, Series 1, No. 14*. June 1978; 110 pages.

Current Estimates From the Health Interview Survey, United States, 1975. *DHEW Publication No. (HRA) 1543, Series 10, No. 115*, March 1977; 74 pages; \$1.40 (Stock No. 017-022-00535-2).

Refraction Status and Motility Defects of Persons 4-74 Years, United States, 1971-1972. *DHEW Publication No. (PHS) 78-1654, Series 11, No. 206*. August 1978; 124 pages.

Total Serum Cholesterol Levels of Children 4-17 Years, United States, 1971-74. *DHEW Publication No. (PHS) 78-1655, Series 11, No. 207*. 1978; 38 pages.

Surgical Operations in Short-Stay Hospitals, United States, 1975. *DHEW Publication No. (PHS) 78-1785, Series 13, No. 34*. April 1978; 68 pages.

Ambulatory Care Utilization Patterns of Children and Young Adults. National Ambulatory Medical Care Survey, United States, January-December 1975. *DHEW Publication No. (PHS) 78-1790, Series 13, No. 39*. August 1978; 43 pages.

Characteristics of Births, United States, 1973-1975. *DHEW Publication No. (PHS) 78-1908, Series 21, No. 30*. September 1978; 49 pages (Stock No. 017-022-00640-5).

Federal publications listed are obtainable from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Orders should be accompanied by check or money order and should identify the publication. (Publications without prices may be obtained from the agency.)

## WORLD HEALTH ORGANIZATION

Induced Abortion. Report of a WHO Scientific Group. *WHO Technical Report Series No. 623*. 1978; 65 pages (ISBN 92 4 120623 3); Geneva. (French and Spanish editions in preparation.)

Surveillance for the Prevention and Control of Health Hazards due to Antibiotic Resistant Enterobacteria. Report of a WHO meeting. *WHO Technical Report Series No. 624*. 1978; 55 pages (ISBN 92 4 120624 1); Geneva. (French and Spanish editions in preparation.)

Financing of Health Services. Report of a WHO Study Group. *WHO Technical Report Series No. 625*. 1978; 117 pages (ISBN 92 4 120625 x); Geneva. (French and Spanish editions in preparation.)

WHO Expert Committee on Biological Standardization. Twenty-Ninth Report. *WHO Technical Report Series No. 626*. 1978; 147 pages (ISBN 92 4 120626 8); Geneva. (French and Spanish editions in preparation.)

Research in Human Reproduction: Strengthening of Resources in Developing Countries. Report of a WHO Study Group. *WHO Technical Report Series No. 627*. 1978; 16 pages (ISBN 92 4 120627 6); Geneva.

Arterial Hypertension. Report of a WHO Expert Committee. *WHO Technical Report Series No. 628*. 1978; 58 pages (ISBN 92 4 120628 4); Geneva. (French and Spanish editions in preparation.)

Poverty, Development, and Health Policy. By B. Abel-Smith with A. Leiserson. *Public Health Papers No. 69*. 1978; 108 pages (ISBN 92 4 130069 8); \$5; Geneva. (French and Spanish editions in preparation.)

Application of the International Classification to Dentistry and Stomatology (ICD-DA). *Second edition*. 1978; 147 pages (ISBN 92 4 154132 6); \$11; Geneva. (French edition in preparation.)

International Public Health Between the Two World Wars—The Organizational Problems. By Norman Howard-Jones. *History of International Health, No. 3*. 1978; 92 pages (ISBN 92 4 156058 4); Geneva. (French edition in preparation.)

Principles and Methods for Evaluating the Toxicity of Chemicals. Part 1. Published under the joint sponsorship of the United Nations Environment Programme and the World Health Organization. *Environmental Health Criteria 6*. 1978; 272 pages (ISBN 92 4 154066 4); Geneva. (French edition in preparation.)

Lay Reporting of Health Information. 1978; 27 pages (ISBN 92 4 154134 2); Geneva. (French edition in preparation.)

Thirty-First World Health Assembly, Geneva, 8-24 May 1978. Part II. Verbatim Records of Plenary Meetings, Summary Records, and Report of Committees. *Official Records of the World Health Organization, No. 248*. 1978; 756 pages (ISBN 92 4 160248 1); Geneva. (Separate editions in English, French, Russian, and Spanish.)

WHO publications may be obtained from WHO Publications Centre USA, 49 Sheridan Ave., Albany, N.Y. 12210.

## NON-FEDERAL

Arthritis: Everybody's Disease. By Arthur S. Freese. *Public Affairs Pamphlet No. 562*. August 1978; 24 pages; 50 cents. *Public Affairs Pamphlets*, 381 Park Ave. South, New York, N.Y. 10016.

Health Effects of Air Pollution. By Carl M. Shy, John R. Goldsmith, Jack D. Hackney, Michael D. Lebowitz, and Daniel B. Menzel. 1978; 48 pages. *American Lung Association* 1740 Broadway, New York, N.Y. 10019.

Environmental Health and Service Aspects of Second Homes: A Survey of Lake Front Properties on Cayuga Lake, Tompkins County, New York. By Mark Andrew Chain. January 1978; 135 pages; \$4.50. *Prehistoric Environmental Health and Human Progress*. By Cheryl A. Russell. May 1978; 25 pages; \$3. *Program in Urban and Regional Studies*, 209 West Sibley Hall, Cornell University, Ithaca, N.Y. 14853.

Systems of Health Care. By Douglas R. Mackintosh. 1978; 326 pages; \$22, paperback \$11.75. *Westview Press*, 5500 Central Ave., Boulder, Colo. 80301.

A Multidisciplinary Approach to Learning Disability. 1978; 104 pages; \$5.95. *American School Health Association*, P.O. Box 708, Kent, Ohio 44240.

Community Health Planning. Identifying Goals and Assessing Achievement. By M. Clinton Miller III, Sara E. Schuh, and Annette Moore. *Biometry Imprint Series, vol. 3*. September 1978; 210 pages; \$18.75 North America, \$21.50 elsewhere (Order No. IS-00059). *University Microfilms International, Monographs Order Entry*, 300 N. Zeeb Rd., Ann Arbor, Mich. 48106.

National Directory of Group Practices. 1978; \$25. *Publications Department, American Group Practice Association*, 20 South Quaker Lane, Alexandria, Va. 22314.

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